



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0529]

Guidance for Industry on Qualification Process for Drug Development Tools; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Qualification Process for Drug Development Tools.” This guidance describes the qualification process for drug development tools intended for potential use, over time, in multiple drug development programs. The guidance provides a framework for interactions between FDA and sponsors to support work towards qualification of an identified drug development tool and creates a mechanism for formal review of data to qualify the tool and ensure that the evaluation is comprehensive and reliable.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shaniece Bowens, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4555, Silver Spring, MD 20993-0002, 301-796-2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Qualification Process for Drug Development Tools.” The guidance describes the qualification process for drug development tools (DDTs) intended for potential use, over time, in multiple drug development programs.

In March 2006, FDA issued the “Critical Path Opportunities Report and List,” in which FDA described six key areas along the critical path to improved therapies and listed specific opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development. Too often, attention to a needed DDT is delayed until the time when the registration study protocols are under development and the available DDTs are inadequate. Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers and patient reported outcome instruments. This guidance describes a formal process that FDA will use in working with sponsors of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory process.

A draft version of this guidance was issued in the Federal Register of October 25, 2010 (75 FR 65495). FDA received a number of comments, most of which focused on clarifications

and further illustration of the qualification process. FDA reviewed all received comments carefully during the finalization process of the guidance; the Agency has made some clarifying changes in the final version of the guidance. Specifically, FDA provided general guidance on the qualification process, samples of what should be included in a qualification package, and examples of drug development tools. A new DDT, Animal Models under the Animal Rule, has been included and discussed in the final DDT guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the qualification process for drug development tools. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The information collection has been approved under the OMB control numbers 0910-0001 and 0910-0014. The information requested in the guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-00028 Filed 01/06/2014 at 8:45 am; Publication Date: 01/07/2014]